IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
HUMANIGEN, INC.,[1]	Case No. 24-10003 (BLS)
Debtor.	**Re. D.I.: 63**
	Hearing Date: February 14, 2024, at 1:30 p.m. **Objection Deadline: February 13, 2024, at 12:00pm[2]**

UNITED STATES' OBJECTION TO DEBTOR'S NOTICE TO COUNTERPARTIES TO POTENTIALLY ASSUMED EXECUTORY CONTRACTS AND UNEXPIRED LEASES REGARDING CURE AMOUNTS AND POSSIBLE ASSIGNMENT TO THE STALKING HORSE BIDDER OR SUCH OTHER SUCCESSFUL BIDDER AT AUCTION

The United States, on behalf of the United States Food and Drug Administration ("FDA"), by and through the undersigned counsel, files this objection and reservation of rights (the "Objection")[3] to the above-captioned Debtor's Assumption Notice.[4] In support of its Objection, the United States avers as follows:

BACKGROUND

1. On January 3, 2024, the Debtor filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Code (the "Bankruptcy Case") [Docket No. 1].

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[1] The Debtor's mailing address in this Chapter 11 case is 533 Airport Boulevard, Suite 400, Burlingame, CA 94010 and the last four digits of the Debtor's federal tax identification number are 7236.

[2] The Debtor granted the United States a deadline extension to file an objection to the Assumption Notice by no later than February 13, 2024, at noon (Eastern Time).

[3] Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Assumption Notice.

[4] *Notice to Counterparties to Potentially Assumed Executory Contracts and Unexpired Leases Regarding Cure Amounts and Possible Assignment to the Stalking Horse Bidder or Such Other Successful Bidder at Auction* [Docket No. 63].

2. Before bankruptcy, the Debtor submitted several Investigational New Drug ("IND") Applications to FDA.

3. On January 4, 2024, the Debtor filed the Sale Procedures Motion.[5] Pursuant to the Sale Procedures Motion, the Debtor requests that this Court approve the sale of substantially all of its assets free and clear and the assumption and assignment of the executory contracts and/or unexpired leases to the Stalking Horse Bidder or such other Successful Bidder. On January 25, 2024, the Court approved the Sale Procedures Motion. *See* Docket No. 65.

4. On January 24, 2024, the Debtor filed the Assumption Notice, identifying certain contracts and agreements that may be assumed and assigned in connection with the proposed sale. The Assumption Notice identifies three INDs (collectively, the "Federal Applications") that the Debtor may seek to assume and assign with the proposed sale.[6] The Assumption Notice lists cure amounts of zero dollar ($0) for each Federal Application.

5. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, is "a Federal law which regulates the manufacture, use, or sale of drugs." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196, 125 S. Ct. 2372, 2377, 162 L. Ed. 2d 160 (2005). Under the FDCA, the Secretary of Health and Human Services delegates primary responsibility over drug regulation to

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[5] *Motion of Debtor for Entry of (I) an Order (A) Approving Bid Procedures in Connection with the Potential Sale of Substantially All of the Debtor's Assets, (B) Scheduling an Auction and a Sale Hearing, (C) Approving the Form and Manner of Notice Thereof, (D) Authorizing the Debtor to Enter Into the Stalking Horse Agreement, (E) Approving Procedures for the Assumption and Assignment of Contracts and Leases, and (F) Granting Related Relief; and (II) an Order (A) Approving the Sale of Substantially All of the Debtor's Assets Free and Clear of All Liens, Claims, Encumbrances, and Interests, (B) Authorizing the Assumption and Assignment of Contracts and Leases, and (C) Granting Related Relief* [Docket No. 10].

[6] While the United States contests the characterization of the Federal Application as executory contract, whether the Federal Applications are executory contracts or other interests has no impact on the limits on the Debtor's ability to transfer and the form and manner of transferring the Federal Application.

the Commissioner of FDA. FDA, among other things, evaluates new drugs, ensures their safety, and evaluates the risks and hazards associated with new drugs. Under the FDCA, a drugmaker must submit research data to FDA at two general stages of new-drug development.

6. First, a drugmaker must submit an IND to FDA to conduct clinical trials (tests on humans). *See* 21 U.S.C. § 355(i); 21 C.F.R. § 312.1 *et seq.* An IND provides a vehicle for FDA to review the effectiveness and safety of a new drug through extensive clinical trials. The IND must describe "preclinical tests (including tests on animals) of [the] drug adequate to justify the proposed clinical testing." 21 U.S.C. § 355(i)(1)(A); *see* 21 C.F.R. § 312.23(a)(5) and (a)(8) (specifying necessary information from preclinical tests). Besides authorizing clinical trials, an IND permits an unapproved drug to cross state lines. Without an IND, the FDCA prohibits unapproved drugs from crossing state lines. *See Investigational New Drug Exemptions: Policy and History*, 1 FOOD AND DRUG ADMIN. § 13:76 (2023) ("The Investigational New Drug Application (IND) is the means through which the sponsor technically obtains [a permission to distribute] a new drug across state lines.").

7. Second, to market a new drug, a drugmaker must submit a new drug application ("NDA"), containing "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A)(i). The NDA must include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties. *See* 21 C.F.R. §§ 314.50(d)(2) (preclinical studies) and (d)(5) (clinical studies).

OBJECTION

8. The Debtor currently holds several INDs monitored and regulated by FDA. If the Debtor seeks to transfer the Federal Applications, the Debtor and the Purchaser must comply with

applicable federal law and regulations, including both bankruptcy law and non-bankruptcy law. *See, e.g., Cinicola v. Scharffenberger*, 248 F.3d 110, 121 (3d Cir. 2001) ("[I]f a contract could not be assigned under applicable law, it may not be assumed or assigned by the [debtor]."); *In re W. Elecs., Inc*., 852 F.2d at 83 ("[Section 365(c)(1)'s prohibition against] assumption of contracts is applicable to any contract subject to a legal prohibition against assignment."); 3 Collier on Bankruptcy P 365.07 (16th 2023) (under § 365(c)(1) of the Bankruptcy Code, "if a contract is of a type that could not be assigned under applicable law, it may not be assumed or assigned by the [debtor].").

9. Although in bankruptcy, the Debtor must comply with FDA regulations, including those regulations addressing the transfer of the Federal Applications. FDA regulations specifically proscribe the manner and method of transferring INDs and NDAs to a new "sponsor."[7] *See* 21 C.F.R. § 314.72(a) (outlining the process to transfer a drug application). FDA regulations also condition any transfer of INDs upon both the former and new sponsors complying "with all applicable requirements . . . with respect to the conduct of the clinical investigations," 21 C.F.R. § 312.40, and other FDA regulatory obligations. *See e.g.,* 21 C.F.R. § 314.72 (providing that while a sponsor may transfer the ownership of an IND, the original and new sponsors must comply with certain requirements and satisfy obligations under FDA regulations); *Withdrawal of Approval of a New Drug Application for BUFFERIN (Aspirin) Tablets*, 88 FR 47147-01, 2023 WL 4641396 (2023) (conditioning the NDA ownership upon the sponsor complying with requirements under 21 C.F.R. § 314.72). Among others, those regulatory obligations include: (i) submitting change of application ownership information to FDA at the time of transfer (21 C.F.R. § 314.72(a)); (ii)

[7] *See* 21 C.F.R. § 312.3 ("Sponsor means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.").

selecting qualified investigators to conduct the proposed clinical trials (21 C.F.R. § 312.50); (iii) ensuring proper monitoring of the drug investigation (21 C.F.R. § 312.56); (iv) promptly informing FDA of any significant new adverse effects or risks with respect to the drug (21 C.F.R. § 312.50); (v) submitting reports to FDA regarding the safety and effectiveness of the drug (21 C.F.R. § 312.56); and (vi) maintaining adequate records relating to the investigational drug (21 C.F.R. § 312.57).

10. The United States objects to any transfer or assumption and assignment the Federal Applications as part of the Sale, unless the Debtor and the Purchaser comply with the specific terms of the Federal Applications and with all applicable non-bankruptcy law, including the FDCA and FDA regulations.

11. Whether pursuing a sale or a plan of reorganization, the Debtor must comply with all FDA rules and regulations, including those governing the transfer of INDs and the obligations thereunder. Any order entered approving the Sale must clearly provide that the Sale does not relieve the Debtor or the Purchaser from their obligations to comply with the FDCA and FDA rules and regulations. Accordingly, the United States objects to the proposed transfer or assumption and assignment of the Federal Applications to the extent the Debtor fails to comply with all applicable non-bankruptcy law.

RESERVATION OF RIGHTS

12. Nothing in this Objection or the United States' participation (or lack thereof) in the Bankruptcy Case, including but not limited to, the Sale Procedures Motion, is intended to be, or should be deemed to be, an admission by the United States that the Federal Applications (or any other document or agreement relating to any such Federal Applications) qualify as an "executory contract" under section 365 of the Bankruptcy Code. The United States reserves all rights and

objections regarding any characterization or treatment of the Federal Applications as executory contracts under section 365 of the Bankruptcy Code.

13. By filing this Objection, the United States does not waive any other rights, claims, actions, defenses, setoffs, or recoupments to which it entitled, including its right to object to the assumption and assignment of the Federal Applications, and all rights, claims, actions, defenses, setoffs, and recoupments are expressly preserved.

14. The United States reserves the right to supplement or otherwise modify this Objection as necessary or appropriate, including to reflect any additional INDs or cure amounts, take discovery and/or respond to any reply filed by the Debtor, any proposed sale order tendered to the Court in connection with a sale hearing, any asset purchase agreement between the Debtor and any Successful Bidder or Back-Up Bidder or any further notice relating to the proposed assumption and assignment and cure amounts of any contracts or agreements between the Debtor and United States. Nothing contained in this Objection constitutes a waiver of any of the claims, defenses, entitlements, rights or remedies of United States, each of which is expressly reserved.

WHEREFORE, the United States requests that the Court require, in any order concerning the assumption or assignment of the Federal Applications or any other federal contract or federal agreement, the consent of the United States in accordance with applicable non-bankruptcy law, and that the Court provide such other and further relief as the Court deems necessary and just.

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Dated: February 13, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 13, 2024, a true and correct copy of the foregoing was served upon: (i) all interested parties via CM/ECF notification system; and (ii) the parties on the list below via email.

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Dated: February 12, 2024

/s/ Jae Won Ha
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